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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/733,756	12/08/2000	David Mack	A-69439/DJB/JJD	2798

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EXAMINER	
GOLDBERG, JEANINE ANNE	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/11/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/733,756	MACK ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, drawn to a method of screening drug candidates by determining the effect of a drug candidate on the expression of CHA4, classified in class 435, subclass 6.

II. Claims 3, 14-15, drawn to method of screening for a bioactive agent capable of binding to CHA4, classified in class 435, subclass 7.1.

III. Claim 4, drawn to method for screening for a bioactive agent capable of modulating the activity of CHA4, classified in class 435, subclass 501.

IV. Claim 5-6, drawn to a method of evaluating the effect of a cancer drug in a patient, classified in class 435, subclass 6.

V. Claims 7, 31, drawn to a method of diagnosing cancer by determining the expression of a nucleic acid, classified in class 435, subclass 6.

VI. Claims 8-13, drawn to an antibody, classified in class 530, subclass 300.

VII. Claim 16-17, drawn to a method of inhibiting the activity of CHA4, classified in class 435, subclass 7.1.

VIII. Claim 18, drawn to a method of neutralizing the effect of a CHA4 by contacting an agent with CHA4 specific agent, classified in class 435, subclass 6 or 435/7.1.

IX. Claims 19-26, 29-30, drawn to a method of treating cancer by administering an inhibitor of CHA4, classified in class 514, subclass 2 or 44, for example.

X. Claim 27, drawn to a method of inhibiting breast cancer by administering an antisense molecule, classified in class 435, subclass 6.

XI. Claim 28, drawn to a biochip comprising nucleic acid, classified in class 536, subclass 23.1.

2. The inventions are distinct, each from the other because of the following reasons:

A) Inventions VI and XI are patentably distinct because the DNA of Group VI and the antibody of Group XI are structurally and functionally distinct. The DNA is composed of nucleotides linked in phosphodiester bonds and arranged in space as a double helix. The DNA can function no only for the expression of the protein but also as a probe in a nucleic acid hybridization assay and in a nucleic acid amplification assay, for example. In contrast, the antibody is composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. The antibody can function for the detection and purification of the polypeptide to which it binds. Therefore these inventions are novel and unobvious over one another.

B) The inventions of Groups I-V, VII-X are patentably distinct methods because they each have different objectives, different uses, different reagents and different method steps. The method of Group I is for a method of screening drug candidates by

determining the effect of a drug candidate on the expression of CHA4. Group II is method of screening for a bioactive agent capable of binding to CHA4. Group III is method for screening for a bioactive agent capable of modulating the activity of CHA4. Group IV is a method of evaluating the effect of a cancer drug in a patient. Group V is a method of diagnosing cancer by determining the expression of a nucleic acid. Group VII is a method of inhibiting the activity of CHA4. Group VIII is a method of neutralizing the effect of a CHA4 by contacting an agent with CHA4 specific agent. Group IX is a method of treating cancer by administering an inhibitor of CHA4. And Group X is a method of inhibiting breast cancer by administering an antisense molecule. Each of these methods rely upon different method steps. For example, Group I is directed to determining the effect of a drug on expression profile gene, namely assaying for a nucleic acid. The methods of treating, Group 9, rely upon administering an antibody. Group X relies upon antisense nucleic acids. Other methods are very general such that the agents may include antibodies, proteins, nucleic acids, antisense. Each of these methods has different objectives, have different method steps and use different products. Therefore the methods are distinct over one another.

C) Inventions VI and (Groups II, VII, VIII, IX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group VI may be used in numerous methods, as exemplified by

the numerous claimed methods involving antibodies. The antibodies may also be used in purification methods.

D) Group XI and Groups (I, V, and X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids on a solid support encoding CHA4 may be used in purification methods, aptamer screening methods, hybridization assays and antisense methods. Additionally, it is noted that numerous distinct methods of the instant application rely upon the CHA4 nucleic acid segment.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by the different classifications and their divergent subject matter, restriction for examination purposes as indicated is proper.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of formal matters can be directed to the patent analyst, Chantae Dessau, whose telephone number is (703) 605-1237.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Goldberg
March 8, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600